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RC

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/027,671 02/23/98 SMITH

A 4292-0048-55

EXAMINER

HM12/0513

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TUNG, M	ART UNIT	PAPER NUMBER
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1644
DATE MAILED:

8
05/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/027,671	Applicant(s) AK Smith, et al.
	Examiner Mary Tung	Group Art Unit 1644

Responsive to communication(s) filed on Apr 15, 1999.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-45 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1-45 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 4/15/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/027,671 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restriction

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-14 and 33-45, are drawn to a method of cell culture, classified in class 435, subclass 375.
 - II. Claims 15-23 are drawn to a cell composition, classified in class 435, subclasses 366, 368, 370, 371, 372 and 372.3.
 - III. Claims 24-32 are drawn to a method of treatment, classified in class 424, subclasses 93.7 and 93.71.
3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case; the product, can be made or obtained by protein purification using an affinity matrix.
4. Groups I and III are unique methods. They differ with respect to ingredients and method steps. A Method of cell culture and a method of treatment represent patentably distinct subject matter. They utilize different reagents, are performed using different steps and produce different outcomes.

5. Groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the cell composition can be used to produce growth factors *in vitro*, for example.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search of any or these three distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

7. Irrespective of whichever group the applicant may elect, the applicant is further required under 35 U.S.C. 121:

8. To elect a **specific human lineage-committed cell**: hematopoietic, mesenchymal, keratinocyte, fibroblast, hepatocyte, neural, epithelial, lymphocyte, osteoblast, osteoclast, stem cell, hematopoietic progenitor cell, mature myeloid cell, stromal cells, dendritic cell, non-myeloid which are other than stromal cells, T cells, or chondrocyte.

9. If group I is elected, the applicant is further required to elect a **specific biological function**: secretion of substances, cell-cell communication, receptor expression on the cell surface, cytolysis, antigen presentation, ability to home *in vivo* to sites for function or the ability to proliferate.

10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 15 and 33 are generic.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. The species are distinct each from the other for the following reasons:
15. Biological functions, such as secretion of substances, cell-cell communication, and so forth, have different biochemical characteristics, activities, target cells and would be measured using different reagents.
16. The specific human lineage-committed cells, such as hematopoietic, mesenchymal, keratinocyte, and so forth are different in the properties, histological appearances and physiological function. Additionally, they are classified in different subclasses.
17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Conclusion

26. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.
26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The examiner can normally be reached Monday through Friday from 8:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

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Art Unit 1644

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Mary B. Tung
May 12, 1999
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 1644